

**Marked-Up Version of Amended Claims 1, 44 and 50-82**

1 (Twice Amended). An apparatus, comprising:

an expandable member being sized to be positionable in a sphincter, the expandable member having a deployed state and a nondeployed state, the deployed state sized and applying sufficient force to the sphincter to dilate the sphincter at least 5 mm;

an energy delivery device coupled to the expandable member, the energy delivery device configured to penetrate tissue and to controllably produce lesions of a sufficient size, number and configuration in an interior of the sphincter so as to create a selectable tightening of the sphincter; and

a flexible coupling member coupled to the expandable member, the coupling member including at least one lumen and configured to be maneuverable in a body lumen.

44 (Amended). An [The] apparatus [of claim 1, further] comprising:

an expandable member being sized to be positionable in a sphincter, the expandable member having a deployed state and a nondeployed state, the deployed state sized and applying sufficient force to the sphincter to dilate the sphincter at least 5 mm;

a visualization device coupled to the expandable member;

an energy delivery device coupled to the expandable member, the energy delivery device configured to controllably produce lesions of a sufficient size, number and configuration in an interior of the sphincter so as to create a selectable tightening of the sphincter; and

a flexible coupling member coupled to the expandable member, the coupling member including at least one lumen and configured to be maneuverable in a body lumen.

50 (Twice Amended). An apparatus comprising:

an expandable member [means] sized to be positionable in a lower esophageal sphincter and non-permanently dilate the lower esophageal sphincter from a contracted state, the expandable member [means] having a deployed state and a nondeployed state, the deployed state sized and applying sufficient force to the sphincter to dilate the sphincter between 5 and 40 mm;

an energy delivery device [means] coupled to the expandable member [means], the energy delivery device [means] configured to penetrate tissue and to controllably produce lesions of a sufficient size, number and configuration in an interior of the lower esophageal

sphincter to create a tightening of the lower esophageal sphincter;

a flexible coupling member [means] coupled to the expandable member [means], the coupling member [means] including at least one lumen [means] and configured to be maneuverable in a body lumen; and,

wherein the lower esophageal sphincter returns to a contracted state upon a removal of the expandable member [means] from the sphincter.

51 (Twice Amended). The apparatus of claim 50, wherein the energy delivery device [means] is configured to controllably produce lesions in an interior of the lower esophageal sphincter without creating a permanent impairment of the lower esophageal sphincter's ability to achieve a physiologically normal state of closure.

52 (Amended). The apparatus of claim 50, wherein the energy delivery device is positioned on an exterior surface of the expandable member [means].

53 (Amended). The apparatus of claim 50, wherein the energy delivery device is positioned on an interior surface of the expandable member [means].

54 (Amended). The apparatus of claim 50, further comprising:  
a lumen [means] positioned in an interior of the expandable member [means].

55 (Amended). The apparatus of claim 50, wherein the expandable member [means] is expandable.

56 (Amended). The apparatus of claim 50, wherein the expandable member [means] is a balloon.

57 (Amended). The apparatus of claim 50, wherein the expandable member [means] is made of an expandable material.

58 (Amended). The apparatus of claim 50, wherein the expandable member [means] is made of a porous material.

59 (Amended). The apparatus of claim 57, further comprising:  
an electrolytic solution [means] housed in an expanded expandable member  
[means].

60 (Twice Amended). The apparatus of claim 50, wherein the energy delivery device [means] is configured to deliver energy to the interior of the lower esophageal sphincter and create a fibroblast proliferation in the interior of the lower esophageal sphincter.

61 (Twice Amended). The apparatus of claim 50, wherein the energy delivery device [means] is configured to deliver energy to the interior of the lower esophageal sphincter and create a myofibroblast proliferation in the lower esophageal sphincter.

62 (Twice Amended). The apparatus of claim 50, wherein the energy delivery device [means] is configured to create a tightening of the lower esophageal sphincter without permanently disrupting an aorta positioned near the lower esophageal sphincter.

63 (Twice Amended). The apparatus of claim 50, wherein the energy delivery device [means] is configured to create a tightening of the lower esophageal sphincter without permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

64 (Twice Amended). The apparatus of claim 50, wherein the energy delivery device [means] is configured to create a tightening of the lower esophageal sphincter without permanently damaging an esophageal plexus of nerves and veins positioned near the lower esophageal sphincter.

65 (Twice Amended). The apparatus of claim 50, wherein the energy delivery device [means] is configured to create a tightening of the lower esophageal sphincter while preserving a blood supply to the lower esophageal sphincter.

66 (Twice Amended). The apparatus of claim 50, wherein the energy delivery device [means] is configured to create a tightening of the lower esophageal sphincter while creating submucosal lesions in the lower esophageal sphincter.

67 (Amended). The apparatus of claim 50, wherein the energy delivery device [means] is an RF electrode [means].

68 (Amended). The apparatus of claim 47, further comprising:  
an RF energy source [means] coupled to the RF electrode [means].

69 (Amended). The apparatus of claim 50, wherein the energy delivery device [means] is a microwave antenna [means].

70 (Amended). The apparatus of claim 69, further comprising:  
a microwave energy source [means] coupled to the microwave antenna [means].

71 (Amended). The apparatus of claim 50, wherein the energy delivery device [means] is a waveguide [means].

72 (Amended). The apparatus of claim 71, further comprising:  
a light source [means] coupled to the waveguide [means].

73 (Amended). The apparatus of claim 72, wherein the light source [means] is a laser [means].

74 (Amended). The apparatus of claim 50, wherein the energy delivery device [means] is an acoustical transducer [means].

75 (Amended). The apparatus of claim 74, further comprising:  
an acoustical energy source [means] coupled to the acoustical transducer [means].

76 (Amended). The apparatus of claim 50, wherein the energy delivery device [means] is a resistive heating device [means].

77 (Amended). An [The] apparatus [of claim 50, further] comprising:  
an expandable member sized to be positionable in a lower esophageal sphincter and

non-permanently dilate the lower esophageal sphincter from a contracted state, the expandable member having a deployed state and a nondeployed state, the deployed state sized and applying sufficient force to the sphincter to dilate the sphincter between 5 and 40 mm;

a visualization device coupled to the expandable member;

an energy delivery device coupled to the expandable member, the energy delivery device configured to controllably produce lesions of a sufficient size, number and configuration in an interior of the lower esophageal sphincter to create a tightening of the lower esophageal sphincter;

a flexible coupling member coupled to the expandable member, the coupling member including at least one lumen and configured to be maneuverable in a body lumen; and,  
wherein the lower esophageal sphincter returns to a contracted state upon a removal of the expandable member from the sphincter.

78 (Twice Amended). The apparatus of claim 50, further comprising:

an extension member [means] coupled to the expandable member [means].

79 (Twice Amended). The apparatus of claim 78, wherein a proximal portion of the extension member [means] is maneuverable by a medical practitioner.

80 (Amended). The apparatus of claim 50, wherein the energy delivery device [means] is a plurality of RF electrodes [means].

81 (Amended). The apparatus of claim 80, wherein the plurality of electrodes [means] is a flexible circuit [means].

82 (Amended). The apparatus of claim 50, further comprising:

a mechanical expansion device [means] coupled to the expandable member [means].

**REMARKS**

The Examiner is provided with a copy of a previously submitted Information Disclosure Statement (Attachment A). The Information Disclosure Statement makes of record references cited in the parent case, Application Serial No. 09/007,237, filed January 14, 1998, now abandoned. A copy of the postcard acknowledging receipt of the Information Disclosure Statement by the Patent and Trademark Office is also provided (Attachment B). The Information Disclosure Statement was not acknowledged in the last office action.

A supplemental Information Disclosure Statement is also submitted herewith. The supplemental Information Disclosure Statement makes of record references cited by the Japanese Examiner in the Japanese counterpart of the instant case.

Claims 1, 44 and 50-82 have been amended. In compliance with 37 C.F.R. §121(c)(3), a clean version of the entire set of pending claims is being submitted, as is a marked-up version showing changes in the amended claims relative to the previous version of the claims.

Claims 1-82 remain in the application. Of these, claims 1, 44, 50 and 77 are independent apparatus claims.

Claims 1-43, 45-76 and 78-82 stand rejected in various combinations under 35 U.S.C. §102(a) as being anticipated by Avitall U.S. Patent No. 5,263,493 and under §102(e) based on Edwards U.S. Patent No. 5,505,730 (Edwards '730), and under 35 U.S.C. §103(a) as obvious over Edwards '730 in view of Edwards et al. U.S. Patent No. 5,558,672. The cited references, alone or combination, do not teach or suggest an energy delivery device that is configured to penetrate tissue (i.e., a tissue-piercing electrode), as defined by amended independent claims 1 and 50 and associated dependent claims.

Claims 44 and 77 have been rewritten in independent form.

Claim 50-82 have been amended to more particularly state the subject matter being claimed.

Claims 1-82 are rejected under 35 U.S.C. §102(f) because the applicant did not invent the claimed subject matter. A petition under 37 C.F.R. §1.48(a) to add inventor David S. Utley was filed on May 16, 2002 (Attachment C). A copy of the postcard acknowledging receipt of the petition by the Patent and Trademark Office is also provided (Attachment D). As previously noted, the claims define subject matter that is distinct from Edwards U.S. 5,505,730. Thus, Applicant believes the listing of different inventors is appropriate.

Serial No. 09/911,874

Amendment A

Claims 1-82 are rejected under the doctrine of obviousness-type double patenting based on claims 1-88 of Edwards U.S. Patent No. 6,056,744 and on claims 1-51 of Edwards et al. U.S. Patent No. 6,254,598 (the '598 Patent). Applicant will submit terminal disclaimers based on the '598 Patent and the '744 Patent upon indication of allowable subject matter, but for the double patenting rejection.

Applicant notes that the Terminal Disclaimer based on Application Serial No. 09/007,283 (the '283 Application) is unacceptable. The Terminal Disclaimer was required during prosecution of the parent case, Application Serial No. 09/007,237, filed January 14, 1998. As the '283 Application is now abandoned, Applicant hereby withdraws the Terminal Disclaimer. The Examiner's attention is directed to related copending Application Serial No. 10/084,590 (the '590 Application), filed February 27, 2002. The '590 Application is a continuation of the '283 Application. A copy of the claims of the '590 Application as currently allowed (Examiner M. Peffley, Art Group 3739) is attached (Attachment E).

Allowance of claims 1-82 is respectfully requested.

Respectfully submitted,

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